(12) UK Patent Application (19) GB (11) 2 364 914 (13) A

(43) Date of A Publication 13.02.2002

(21) Application No 0018177.6

(22) Date of Filing 26.07.2000

(51) INT CL[7]
A61L 2/14 // A61L 2/20 101:10 101:32 101:36

(52) UK CL (Edition T)
A5G G101 G102

(56) Documents Cited
GB 2177020 A
US 5876666 A
US 5674450 A
WO 97/18343 A
US 5785934 A
US 4265747 A

(58) Field of Search
UK CL (Edition R) A5G GAB
INT CL[7] A61L 2/14 2/20 , B65B 55/00 55/02
On-line : WPI, EPODOC, JAPIO

(71) Applicant(s)
Jacques Protic
Bryn Du, Llanbedrgoch, Isle of Anglesey, LL76 8NX, United Kingdom

(72) Inventor(s)
Jacques Protic

(74) Agent and/or Address for Service
Potts, Kerr & Co
15 Hamilton Square, BIRKENHEAD, Merseyside, CH41 6BR, United Kingdom

(54) Abstract Title
Sterilisation

(57) Sterilisation is performed in an apparatus without the process being carried out in a vacuum. The process involves providing a sterilisation chamber or area 11 with formalin as a gaseous sterilising agent and creating a plasma from the sterilising agent. Following sterilisation, any harmful residue may be neutralised, e.g. by introducing ozone into the sterilisation area or by passing the residue through a carbon filter. The process provides an improved sterilisation method the efficiency of which is unaffected by trace moisture and which can be used for sterilising large volumes such as rooms.

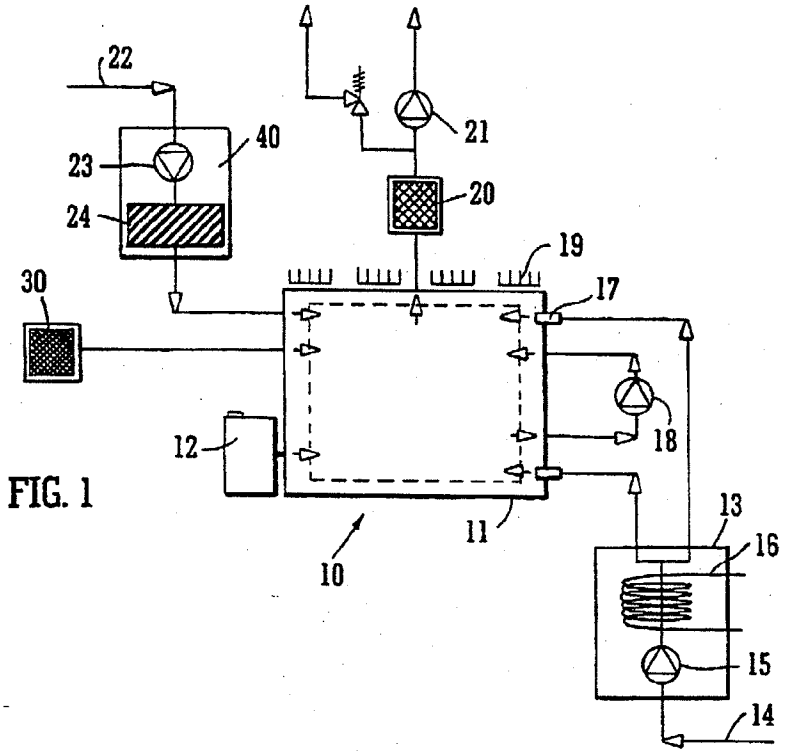

FIG. 1

GB 2 364 914 A

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

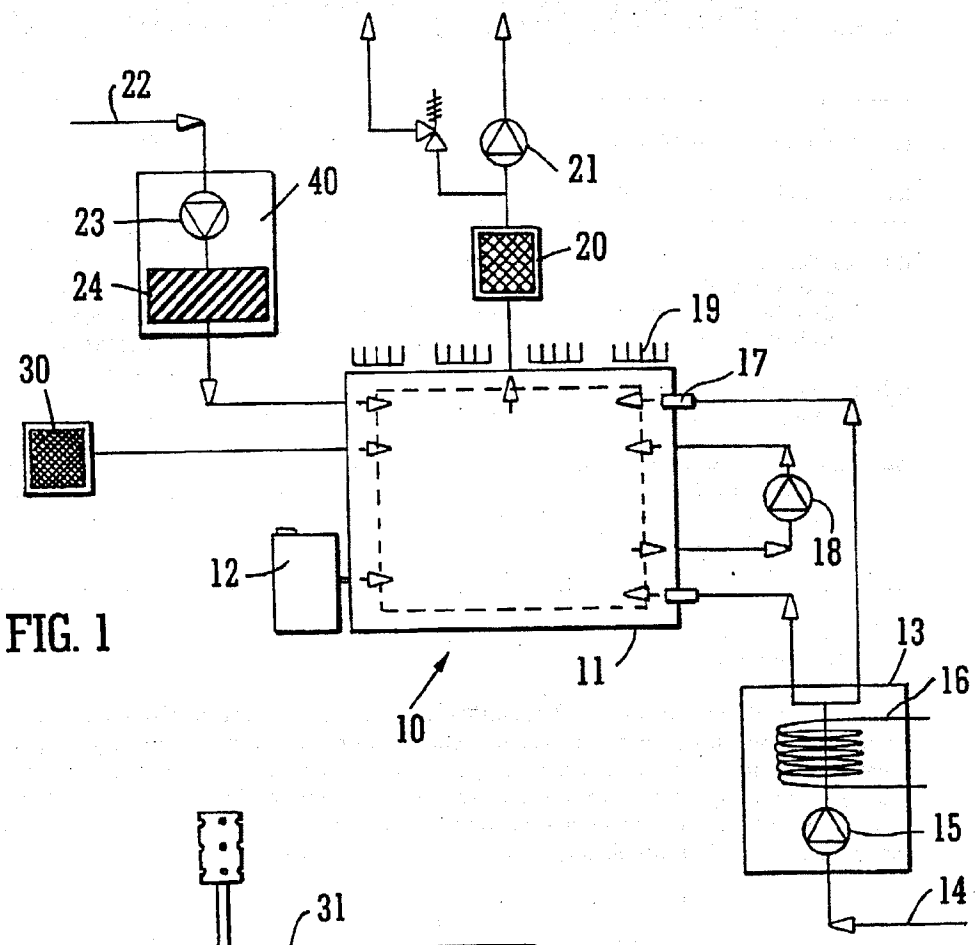

FIG. 1

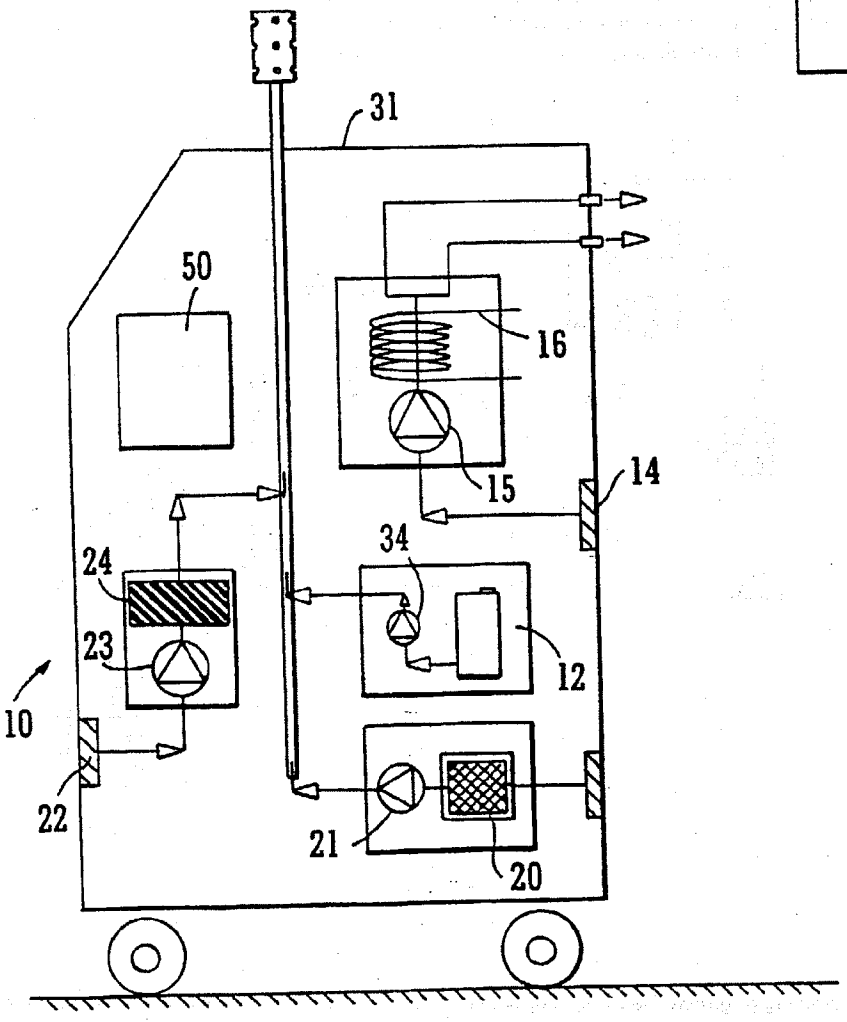

FIG. 2

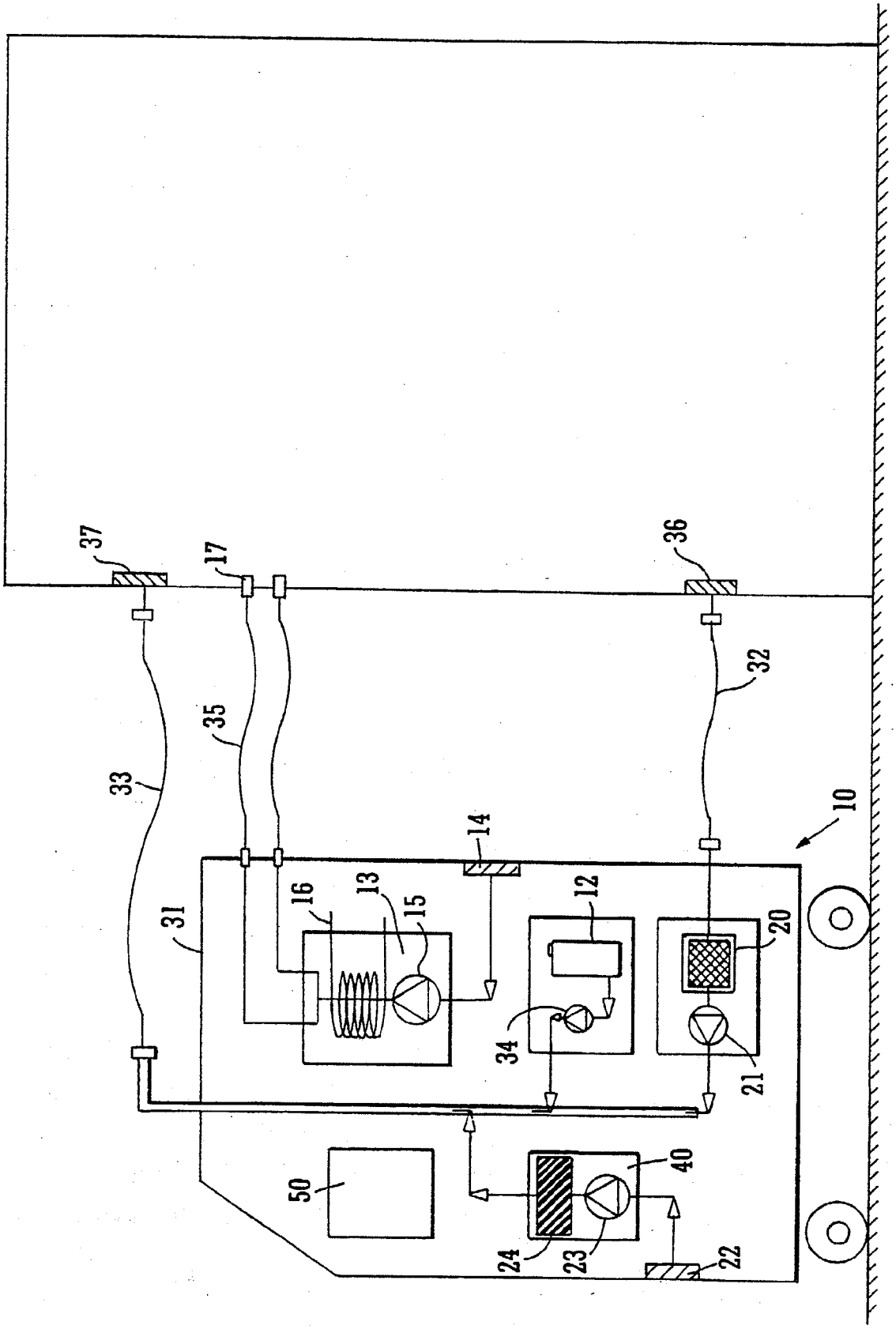

FIG. 3

A STERILISATION PROCESS AND APPARATUS THEREFOR

The present invention relates to a sterilisation process. In particular, the present invention relates to a sterilisation process that does not need to be carried out in a vacuum. Additionally, the present invention relates to an apparatus therefor.

As will be appreciated, it is imperative that materials and devices used for the practice of medicine are aseptic.

As a result thereof, much research has gone into the development of processes suitable for effecting sterilisation of such materials and devices.

Generally, such processes are carried out by the manufacturer of such materials and devices, or by users thereof, for example, by medical establishments, such as hospitals.

One sterilisation process currently being utilised involves exposing such materials and devices to ethylene oxide gas for at least one hour and then leaving same to aerate for a minimum period of twelve hours. As is well documented, one of the major problems associated with the use of ethylene oxide gas is that it is highly toxic and dangerous to humans, that is, it is a known carcinogen and mutagen. Additionally, and due to the aeration time required, it is time consuming.

Another low temperature sterilisation process involves treating, by irradiation, the materials and devices with Gamma radiation. Although such process overcomes the disadvantages associated with the use of ethylene oxide, it will be appreciated that the apparatus therefor is extremely expensive and more importantly, it cannot be used to sterilise any electro medical

devices or items, since any item including a memory chip is simply wiped clean by the action of Gamma radiation thereon.

Another sterilisation process involves the use of steam autoclaving. As will be appreciated by those skilled in the art, one of the problems associated with the use of such a process is that it requires high temperatures and therefore, is not suitable for sterilising materials or devices made out of matter that is affected by either moisture or high temperature, i.e. its application is fairly limited and depends on the inherent nature of the matter out of which the material or device to be sterilised is made.

With a view to overcoming the problems associated with the sterilisation processes outlined above, a number of low temperature sterilisation processes, involving the use of gas plasma, have been developed.

One of the first sterilisation systems involving the use of gas plasma that received approval from the Food and Drug Administration (FDA) was the STERAD sterilisation system manufactured by Advanced Sterilisation Products, a division of Johnson and Johnson. Such system operates as follows:

Items to be sterilised are placed into the sterilisation chamber of the STERAD steriliser and air is evacuated therefrom to produce a vacuum. When a sufficiently low pressure is achieved within the chamber, a low temperature air plasma is generated to aid with the removal of any residual moisture from the items being sterilised. This is known as the pre-plasma stage.

At the end of the pre-plasma stage, the system is vented to atmospheric pressure by the introduction of filtered air. This process step

constitutes the end of the pre-treatment drying phase, and the sterilisation process then begins.

To start sterilisation, the pressure within the chamber is reduced and an aqueous solution of hydrogen peroxide is injected into and vaporized within the chamber. The resulting hydrogen peroxide vapour diffuses through the chamber thereby surrounding the items to be sterilised and initiating the inactivation of the microorganisms.

The pressure within the chamber is then increased, and then following a subsequent pressure reduction, a low temperature plasma is generated by applying RF energy to create an electric field that in turn initiates the generation of the plasma. In the plasma, the hydrogen peroxide vapour is broken apart into reactor species known as free radicals. After the activated components react with the organisms, other materials, or each other, they lose their high energy and recombine to form oxygen, water vapour and other non-toxic by-products. This constitutes one half of the total sterilisation process, which is then completed by repeating the above steps, that is, with the exception of repeating the pre-treatment drying phase.

At the completion of the second half cycle, the RF energy is turned off, the vacuum is released, and the chamber is returned to atmospheric pressure by the introduction of HEPA-filtered air.

Although widely used, the STERAD apparatus and process exhibits the following disadvantages:

A. Moisture interferes with the STERAD steriliser's ability to attain vacuum conditions. As a result thereof, the presence of excess moisture will result in the STERAD apparatus aborting the sterilising process being carried out therein;

B. Sterilisation will not occur if any organic material is present, since the sterilising agent will decompose. This results in the necessity of ensuring that the items to be sterilised are thoroughly clean before being placed in the STERAD steriliser. As will be appreciated, this is time consuming;

C. The STERAD steriliser cannot sterilise items having long (greater than 12 inches) or narrow lumens without the assistance of a "diffusion intensifier". As will be appreciated, such a constraint limits the STERAD steriliser's utility;

D. The items to be sterilised can only be packaged, or wrapped, in polypropylene sterilisation wrap or polypropylene pouches. In this connection, the STERAD system cannot achieve sterilisation of items wrapped in tear-proof paper, which is the standard packaging material used extensively in hospitals. The reason being is that the hydrogen peroxide, which is in droplet form, would be absorbed by the tear proof paper wrapping thereby making the STERAD process ineffective. As a result thereof, it is recommended that users of the STERAD steriliser use a special and considerably more expensive synthetic wrapping made by Du Pont and sold under the trade mark, Tyvek;

E. As with other sterilisation processes involving the use of hydrogen peroxide, liquids, powders and absorptive materials, such as paper, cannot be sterilised due to their tendency to absorb hydrogen peroxide. As will be appreciated, such absorption hinders sterilisation efficiency and aeration of the sterilant;

F. As a vacuum is required to carry out the STERAD process, the size of the sterilising chamber is limited. As will be appreciated, this makes the STERAD steriliser suitable for relatively small volume process applications only; and

G. It has been documented that hydrogen peroxide is not as penetrating as ethylene oxide.

According to the present invention, there is provided a sterilisation process which is not carried out in a vacuum including the steps of:

providing a sterilisation chamber or area to be sterilised with a sterilising agent in a gaseous state; and

creating plasma from the sterilising agent.

It is believed that the sterilisation process of the present invention at least addresses some of the disadvantages associated with the STERAD process outlined above. In particular, and since the process of the present invention is not carried out in a vacuum, the presence of small traces of moisture does not inhibit sterilisation. Furthermore, as the sterilisation process of the present invention does not need to be carried out in a vacuum, it can be utilized for large volume applications, for example, it can be utilised to sterilise laboratory rooms, bio-hazardous areas and similar environments or enclosures. Moreover, the process of the present application is still effective even when the materials or devices to be sterilised are soiled. In this connection, and during our investigations, we smeared items to be sterilised with egg yolk and observed that same had no effect on the effectiveness of the process of the present invention. Consequently, it is believed that the process of the present invention is more penetrating and moreover, does not require a pre-sterilising check to ensure that the items to be sterilised are thoroughly clean.

In a preferred embodiment, the sterilising agent is formalin, that is, formaldehyde in gaseous state. Further preferably, the sterilisation chamber area to be sterilised is provided with formalin at a concentration of 2000 – 6000 parts of a million (ppm), further preferably, 3000 ppm. One of the main advantages of using formalin is that same can be utilised with both standard

paper wrapping and synthetic specialised wrappings like Tyvek, since formaldehyde is readily evaporated by exposure to elevated temperatures.

In a preferred embodiment, and subsequent to the production of plasma, the sterilisation process in accordance with the present invention includes the step of neutralising the gaseous matter or harmful residue. In this connection, and when the sterilising agent is formalin, neutralisation is effected by introducing ozone into the sterilising chamber or area to be sterilised, which will convert any formalin gas residue into carbon dioxide and tiny traces of harmless formic acid. Further preferably, and in addition to, or instead of, the addition of ozone, the residue may be neutralised by passing same through a carbon filter. In this connection, it is preferable that the sterilisation chamber or area to be sterilised is flushed with air drawn through a ULPA or HEPA filter.

In an alternative preferred embodiment, the sterilising agent is peracetic acid, preferably having a concentration of 5% w/w (weight for weight). In this alternative preferred embodiment, ozone is preferably introduced into the sterilising chamber or area to be sterilised to enhance sterilisation. Additionally, when the sterilising agent is peracetic acid, the sterilisation process, subsequent to the production of plasma, further includes the step of neutralising the gaseous matter or harmful residue remaining within the sterilising chamber or area to be sterilised, preferably by passing same through a carbon filter. In this connection, it is preferable that the sterilisation chamber or area to be sterilised is flushed with air drawn through a ULPA or HEPA filter.

In a preferred embodiment, prior to creating plasma from the gaseous sterilising agent, the sterilising agent is re-circulated within the sterilisation chamber or area to be sterilised for a period of 5 to 15 minutes, preferably 10 minutes. It is believed that such re-circulation provides optimum initial exposure of the sterilising agent to the microorganisms to be eradicated.

Further preferably, the plasma is produced or generated for 15 – 180 minutes, preferably 45 minutes. It is believed that such duration is sufficient to enable the required interaction between the free radicals produced within the plasma field and the vital cell components, such as cell membranes, enzymes and nucleic acids, such that the life functions of the organisms to be eradicated is disrupted.

Further preferably, during the plasma producing stage, gas within the sterilisation chamber or area to be sterilised is re-circulated to give maximum exposure.

Further preferably, and during the production of plasma, additional oxygen electrons or free radicals are introduced into the sterilisation chamber or area to be sterilised. Preferably, this is effected by drawing air and/or oxygen into the sterilisation chamber or area to be sterilised.

In a preferred embodiment, during the production of plasma, the temperature within the sterilisation chamber or area to be sterilised is maintained from 25 °C to 66 °C, preferably at 50 °C or within +/-3 °C thereof. By varying the temperature, it will be appreciated that the internal pressure within the sterilisation chamber or area to be sterilised will correspondingly change thereby enabling better penetration of items that need to be sterilised, even items which are wrapped.

In a preferred embodiment, the temperature within the sterilisation chamber or area to be sterilised prior to the production of plasma is maintained from 22 °C to 45 °C. During our investigations we noted that an increase of temperature prior to the introduction of the gaseous sterilising agent, in particular, formalin, improved the effectiveness of the sterilising agent. In particular, we observed that the effectiveness of formalin was

increased when the sterilisation chamber or area to be sterilised was maintained at a temperature of 45°C.

In a further aspect of the present invention there is provided a sterilisation apparatus when used to carry out the sterilisation process of the present invention, the sterilisation apparatus being provided with a sterilisation chamber or being connectable to an area to be sterilised and including:

means for providing the sterilisation chamber or area to be sterilised with a sterilising agent in a gaseous state; and

means for creating plasma within the sterilisation chamber or area to be sterilised from the sterilising agent.

In a preferred embodiment the plasma generating means are isolated such that they cannot come into contact with the items to be sterilised. This has the advantage in that a sterilisation apparatus in accordance with the present invention is less likely to short circuit. That is, and as will be appreciated by those skilled in the art, since the plasma generating electrodes of the Sterad apparatus are an integral part of the sterilisation chamber's inner walls same is more prone to short circuiting due to the metal items to be sterilised coming into contact therewith. This being the reason why the proprietors of the Sterad apparatus state that any metal items must be kept from coming into contact with the sterilisation chamber's inner or internal walls.

The following non-limiting embodiments of a sterilising apparatus in accordance with the present invention are given by way of example, and with reference to, the accompanying drawings in which:

Figure 1 is a cross-sectional view of a first embodiment of a sterilisation apparatus in accordance with the present invention;

Figure 2 is a cross-sectional view of a second portable sterilisation apparatus in accordance with the present invention; and

Figure 3 is a cross-sectional view of the sterilisation apparatus of Figure 2 when being utilised to sterilise a room.

As illustrated in Figure 1, a sterilisation apparatus 10 in accordance with the present invention includes a sterilisation chamber 11 into which the items to be sterilised can be located.

The sterilisation chamber 11 is in communication with a chemical dosing unit 12, which, in use, dispenses the sterilising agent, for example, formalin or peracetic acid, in a gaseous state thereinto. In this connection, and if the sterilising agent is formalin, then same is introduced by heat evaporation of formaldehyde. Alternatively, and if the sterilising agent is peracetic acid then same is introduced as an aerosol.

Within the sterilisation chamber 11 there are two plasma electrodes 17 that are attached to a plasma generator 13, which includes an air inlet 14, an air pump 15 for drawing air into the plasma generator 13 and a HF transformer 16. It is to be understood that the number of plasma electrodes 17 may be varied depending on the volume of the sterilisation chamber or area to be sterilised, for example, if the sterilisation chamber or area to be sterilised is large, then there may be 4-6 plasma electrodes. Preferably, the electrodes 17 enter the sterilisation chamber 11 via isolated and sealed apertures.

The sterilisation chamber 11 is further provided with, or connectable to, a re-circulation system 18 for pumping or re-circulating the air within the sterilisation chamber 11.

The sterilisation chamber 11 is further associated with heat absorption cooling modules 19, which, in use, are used to cool the sterilisation chamber 11 such that the temperature within the chamber 11 can be maintained at a desired level.

An ozone generator 40 is also associated with the sterilisation chamber 11. Such generator 40 includes an air inlet 22, an air pump 23 and an ozone unit 24. In use, the air pump 23 draws dry air into the generator 40 via the air inlet 22 and pumps the air through the ozone unit 24 and into the sterilisation chamber 11. In this connection, it is to be understood that the dry air can be drawn directly from a supply of pure oxygen, for example, from a canister of oxygen that is connected to the air inlet 22.

The sterilisation chamber 11 is further associated with an extraction system including an activated carbon filter 20 and an air pump 21. In use, and after the generation of plasma, any harmful residue can be neutralised by extraction through the carbon filter 20. In this connection, and so that the sterilisation chamber can be flushed with clean air, same is connected to an ULPA filter 30. It is to be understood that a HEPA filter can be used instead of, or in addition to, a ULPA filter.

A, non-limiting, example of a sterilisation process in accordance with the present invention being carried out by the sterilisation apparatus of Figure 1 is as follows:

The sterilisation chamber 11 was loaded, that is, in accordance with ISO 11138, BS EN 866, EN ISO 14937 (draft), BS EN 1174, ISO 14161 (draft) and other relevant documents with microorganism load ranging from 10^{log4} to 10^{log6}.

Formalin gas at a concentration of 3000 ppm was then introduced from the chemical dosing unit 12 into the sterilisation chamber 11.

The temperature, which was previously ambient, was increased from 22 °C to 45 °C, and the formalin gas was re-circulated via the re-circulation system 18 for 10 minutes within the chamber 11.

The gas plasma electrodes 17 of the plasma generator 13 were fired up directly into the formalin gas field to produce plasma therefrom for 45 minutes. During plasma generation, the temperature within the sterilisation chamber was increased to 50 °C and maintained to within +/-3°C thereof by the heat absorption cooling modules 19.

After 30 minutes, the gas plasma electrodes 17 were switched off and the ozone generator 40 was activated for approximately 10 minutes introducing 0.31 grams of ozone to neutralise the chamber's gas contents into carbon dioxide and minute traces of formic acid.

Finally, the air pump 21 of the extraction system was activated thereby drawing clean air into the sterilisation chamber 11 via the ULPA filter 30 and discharging the neutralised residue back into the lab via an activated carbon filter 20. Such extraction and neutralisation lasted for 5 minutes.

The biological indicators were then removed and then incubated in accordance with standard procedure to establish sterility level. In this connection, and even when the biological indicators were wrapped, we consistently achieved the required sterility level, namely, a Sterility/Sterilisation Assurance Limit (SAL) of 10^{-6}.

As illustrated in Figures 2 and 3, a second embodiment of a sterilisation apparatus 10 in accordance with the present invention, which is portable, includes a wheeled housing 31 housing the working components thereof.

As illustrated such apparatus 10, can be connected to, or associated with, a room 11, which, in effect is the sterilisation chamber. That is, anything within the room 11 can be sterilised. Said room being provided with an

inlet 36 and outlet 37 to which the working components of the sterilisation apparatus 10 can be attached.

Such apparatus 10 includes a chemical dosing unit 12, which, in use, can dispense the sterilising agent, for example, formalin or peracetic acid, in a gaseous state, via a hose or pipe 32, that is, by the action of pump 34, into the room 11 via inlet 36.

Within the room 11 there are plasma electrodes 17, which are attached to a plasma generator 13, via cables 35. Such plasma generator 13 includes an air inlet 14, an air pump 15 for drawing air into the plasma generator 13 and a HF transformer 16. It is to be understood that the room 11 or area to be sterilised can be provided with the plasma electrodes 17 such that the sterilisation apparatus 10 can be simply connected thereto, or that a wall or walls of the room 11 are provided with an aperture through which the plasma electrodes 17 may protrude so that they are suitably located within the room 11. In any event, it is preferable that the plasma electrodes 17 are isolated and sealed such that they cannot come into direct contact with the items to be sterilised.

Air within the room 11 is re-circulated by air pump 21, which, in use, pumps air via flexible pipes 32 and 33 into and out of the room through inlet 36 and outlet 37 respectively.

The sterilisation apparatus 10, in this embodiment, is further provided with a gas analysing and monitoring support system 50, which, in use, can monitor the process parameters.

The housing further houses an ozone generator 40. Such generator 40 includes an air inlet 22, an air pump 23 and an ozone unit 24. In use, the air pump 23 draws dry air, preferably pure oxygen from a gas canister, into the generator 40 via the air inlet 22 and pumps the air through an air dryer and

then through the ozone unit 24 and into the room 11 via flexible pipe 32 and inlet 36.

The sterilisation apparatus 10 is further provided with an extraction system including an activated carbon filter 20 and an air pump 21. In use, and after the generation of plasma, any harmful residue can be neutralised by extracting the gaseous contents of the room 11, via outlet 37 and flexible pipe 33, through the carbon filter 20.

A non-limiting example of the sterilising process in accordance with the present invention utilising the sterilising apparatus of Figures 2 and 3 will now be exemplified below:

A single occupancy hospital ward 11 was artificially seeded with MRSA (Staphylococcus Aureus (Oxford Strain)) with a 100,000 colony forming units (cfu).

The sterilising apparatus 10 was connected or linked to the ward 11. In this connection, the flexible pipes 33 and 32 were connected to an outlet 37 and inlet 36 provided in the wall of such ward 11 respectively.

The connector cables 35, which are connected to the gas plasma electrodes 17, located within the ward 11, were then connected to the plasma generator 13 of the sterilising apparatus 10. Due to the size of the ward 11 the gas plasma generator 13 was nearly three times the power of the first embodiment outlined above, for example, 600 watts.

Formalin gas at a concentration of 3000 ppm was then introduced from the chemical dosing unit 12 into the ward 11, that is, via pipe 32 and inlet 36.

The temperature, which was previously ambient, was increased from 22 °C to 27 °C, and the formalin gas was re-circulated via the re-circulation system 18 for 10 minutes within the ward 11.

The plasma generator 13 was then activated and left to run for 3 hours.

Neutralisation was effected by 30 minutes of ozone generation, which was fed into the ward 11 via flexible hose 32 connected to inlet 36.

There was then twenty air changes via the activated carbon filters 20 prior to re-entering the ward 11.

On entering the room, we collected all the randomly sited Staphylococcus and then incubated same for 24 hours. On doing so, no growth was recorded in any of the samples, except the control.

CLAIMS

1. A sterilisation process which is not carried out in a vacuum including the steps of:

providing a sterilisation chamber or area to be sterilised with a sterilising agent in a gaseous state; and

creating plasma from the sterilising agent.

2. A sterilisation process as claimed in claim 1, wherein the sterilising agent is formalin.

3. A sterilisation process as claimed in claim 2, wherein the sterilisation chamber or area to be sterilised is provided with formalin at a concentration of 2000-6000 ppm.

4. A sterilisation process as claimed in claim 3, wherein the sterilisation chamber or area to be sterilised is provided with formalin at a concentration of 3000 ppm (parts per million).

5. A sterilisation process as claimed in any one of claims 1 to 4, wherein the sterilisation process, subsequent to the production of plasma, further includes the step of neutralising any harmful residue within the sterilising chamber or area to be sterilised.

6. A sterilisation process as claimed in claim 5, wherein the harmful residue is neutralised by the introduction of ozone into the sterilising chamber or area to be sterilised.

7. A sterilisation process as claimed in claim 5 or 6, wherein the harmful residue is neutralised by passing same through a carbon filter.

8. A sterilisation process as claimed in claim 1, wherein the sterilising agent is peracetic acid.

9. A sterilisation process as claimed in claim 8, wherein the peracetic acid has a concentration of 5% w/w.

10. A sterilisation process as claimed in claim 8 or 9, wherein ozone is also introduced into the sterilising chamber or area to be sterilised to enhance sterilisation.

11. A sterilisation process as claimed in any one of claims 8 to 10, wherein the sterilisation process, subsequent to the production of plasma, further includes the step of neutralising any harmful residue within the sterilising chamber or area to be sterilised.

12. A sterilisation process as claimed in claim 11, wherein the harmful residue is neutralised by passing same through a carbon filter.

13. A sterilisation process as claimed in any one of the preceding claims, wherein prior to creating plasma from the gaseous sterilising agent, the sterilising agent is re-circulated within the sterilising chamber or area to be sterilised for a period of 5 to 15 minutes.

14. A sterilisation process as claimed in claim 13, wherein the sterilising agent is re-circulated for a period of 10 minutes.

15. A sterilisation process as claimed in any one of the preceding claims, wherein plasma is produced for 15-180 minutes.

16. A sterilisation process as claimed in claim 15, wherein the plasma is produced for 45 minutes.

17. A sterilisation process as claimed in claim 15 or 16, wherein during the duration of the plasma producing stage, the air within the sterilisation chamber or area to be sterilised is re-circulated.

18. A sterilisation process as claimed in any one of claims 15 to 17, wherein during the production of plasma the temperature within the sterilisation chamber or area to be sterilised is maintained from 25°C to 66°C.

19. A sterilisation process as claimed in 18, wherein during the production of plasma the temperature within the sterilisation chamber or area to be sterilised is maintained at 50°C or within +/- 3°C thereof.

20. A sterilisation process as claimed in any one of the preceding claims, wherein the temperature within the sterilisation chamber or area to be sterilised prior to the production of plasma is maintained from 22°C to 45°C.

21. A sterilisation process substantially as hereinbefore described and exemplified.

22. A sterilisation apparatus when used to carry out the sterilisation process as claimed by any one of the preceding claims, the sterilisation apparatus being provided with a sterilisation chamber or being connectable to an area to be sterilised and including:

means for providing the sterilisation chamber or area to be sterilised with a sterilising agent in a gaseous state; and

means for creating plasma within the sterilisation chamber or area to be sterilised from the sterilising agent.

23. A sterilisation apparatus as claimed in claim 22, wherein the sterilisation apparatus further includes means for effecting re-circulation of the air within the sterilisation chamber or area to be sterilised.

24. A sterilisation apparatus as claimed in claims 22 or 23, wherein the sterilisation apparatus further includes means for neutralising any harmful residue within the sterilisation chamber or area to be sterilised.

25. A sterilisation apparatus as claimed in claim 24, wherein the means for neutralising the harmful residue, subsequent to the production of plasma, include ozone producing means which dispense ozone into the sterilisation chamber or area to be sterilised.

26. A sterilisation apparatus as claimed in claim 25, wherein the ozone generating means can generate ozone at a rate of 1.5 – 1.9 grams per hour.

27. A sterilisation apparatus as claimed in claim 24 or 26, wherein the neutralisation means include a carbon filter through which air from the sterilisation chamber or area to be sterilised is drawn.

28. A sterilisation apparatus as claimed in claims 24 to 27, wherein the neutralisation means includes means for flushing the sterilisation chamber or area to be sterilised with clean air.

29. A sterilisation apparatus as claimed in claim 28, wherein the means for flushing the sterilisation chamber or area to be sterilised with clean air include a ULPA filter through which air from outside the sterilisation chamber or area to be sterilised is drawn.

30. A sterilisation apparatus as claimed in any one of claims 22 to 29, wherein the sterilisation apparatus is portable.

31. A sterilisation apparatus as claimed in claim 30, wherein the sterilisation apparatus is provided with wheels such that same can be wheeled from one location to another.

32. A sterilisation apparatus as claimed in any one of claims 22 to 31, wherein the power of the means for producing plasma ranges from 200 – 1200 watts.

33. A sterilisation apparatus as claimed in any one of claims 22 to 32, wherein the plasma generating means are isolated and/or sealed such that they cannot come into direct contact with the items to be sterilised.

34. A sterilisation apparatus substantially as hereinbefore described with reference to the accompanying drawings.

Amendments to the claims have been filed as follows

1. A sterilisation process which is not carried out in a vacuum including the steps of:

providing a sterilisation chamber or area to be sterilised with a sterilising agent in a gaseous state; and

creating plasma from the sterilising agent, wherein the sterilising agent is formalin.

2. A sterilisation process as claimed in claim 1, wherein the sterilisation chamber or area to be sterilised is provided with formalin at a concentration of 2000-6000 ppm.

3. A sterilisation process as claimed in claim 2, wherein the sterilisation chamber or area to be sterilised is provided with formalin at a concentration of 3000 ppm (parts per million).

4. A sterilisation process as claimed in any one of claims 1 to 3, wherein the sterilisation process, subsequent to the production of plasma, further includes the step of neutralising any harmful residue within the sterilising chamber or area to be sterilised.

5. A sterilisation process as claimed in claim 4, wherein the harmful residue is neutralised by the introduction of ozone into the sterilising chamber or area to be sterilised.

6. A sterilisation process as claimed in claim 4 or 5, wherein the harmful residue is neutralised by passing same through a carbon filter.

7. A sterilisation process as claimed in any one of the preceding claims, wherein prior to creating plasma from the gaseous sterilising agent, the sterilising agent is re-circulated within the sterilising chamber or area to be sterilised for a period of 5 to 15 minutes.

8. A sterilisation process as claimed in claim 7, wherein the sterilising agent is re-circulated for a period of 10 minutes.

9. A sterilisation process as claimed in any one of the preceding claims, wherein plasma is produced for 15-180 minutes.

10. A sterilisation process as claimed in claim 9, wherein the plasma is produced for 45 minutes.

11. A sterilisation process as claimed in claim 9 or 10, wherein during the duration of the plasma producing stage, the gas within the sterilisation chamber or area to be sterilised is re-circulated.

12. A sterilisation process as claimed in any one of claims 9 to 11, wherein during the production of plasma the temperature within the sterilisation chamber or area to be sterilised is maintained from 25°C to 66°C.

13. A sterilisation process as claimed in 12, wherein during the production of plasma the temperature within the sterilisation chamber or area to be sterilised is maintained at 50°C or within +/- 3°C thereof.

14. A sterilisation process as claimed in any one of the preceding claims, wherein the temperature within the sterilisation chamber or area to be sterilised prior to the production of plasma is maintained from 22°C to 45°C.

15. A sterilisation process as claimed by any one of claims 1 to 14 substantially as hereinbefore described and exemplified.

16. A sterilisation apparatus when used to carry out the sterilisation process as claimed by any one of the preceding claims, the sterilisation apparatus being provided with a sterilisation chamber or being connectable to an area to be sterilised and including:

means for providing the sterilisation chamber or area to be sterilised with a sterilising agent in a gaseous state; and

means for creating plasma within the sterilisation chamber or area to be sterilised from the sterilising agent.

17. A sterilisation apparatus as claimed in claim 16, wherein the sterilisation apparatus further includes means for effecting re-circulation of the air within the sterilisation chamber or area to be sterilised.

18. A sterilisation apparatus as claimed in claims 16 or 17, wherein the sterilisation apparatus further includes means for neutralising any harmful residue within the sterilisation chamber or area to be sterilised.

19. A sterilisation apparatus as claimed in claim 18, wherein the means for neutralising the harmful residue, subsequent to the production of plasma, include ozone producing means which dispense ozone into the sterilisation chamber or area to be sterilised.

20. A sterilisation apparatus as claimed in claim 19, wherein the ozone generating means can generate ozone at a rate of 1.5 – 1.9 grams per hour.

21. A sterilisation apparatus as claimed in claim 18 or 20, wherein the neutralisation means include a carbon filter through which air from the sterilisation chamber or area to be sterilised is drawn.

22. A sterilisation apparatus as claimed in claims 18 to 21, wherein the neutralisation means includes means for flushing the sterilisation chamber or area to be sterilised with clean air.

23. A sterilisation apparatus as claimed in claim 22, wherein the means for flushing the sterilisation chamber or area to be sterilised with clean air include a ULPA filter through which air from outside the sterilisation chamber or area to be sterilised is drawn.

24. A sterilisation apparatus as claimed in any one of claims 16 to 23, wherein the sterilisation apparatus is portable.

25. A sterilisation apparatus as claimed in claim 24, wherein the sterilisation apparatus is provided with wheels such that same can be wheeled from one location to another.

26. A sterilisation apparatus as claimed in any one of claims 16 to 25, wherein the power of the means for producing plasma ranges from 200 – 1200 watts.

27. A sterilisation apparatus as claimed in any one of claims 16 to 26, wherein the plasma generating means are isolated and/or sealed such that they cannot come into direct contact with the items to be sterilised.

28. A sterilisation apparatus substantially as hereinbefore described with reference to the accompanying drawings.

The Patent Office
PATENTS • DESIGNS • COPYRIGHT • TRADE MARKS
INVESTOR IN PEOPLE

Application No: GB 0018177.6 Q24 **Examiner:** Graham S. Lynch
Claims searched: 1 to 34 **Date of search:** 23 November 2000

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.R): A5G (GAB)

Int Cl (Ed.7): A61L 2/14, 2/20; B65B 55/00, 55/02

Other: On-line : WPI, EPODOC, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X	GB 2177020 A	SHINRYO. Whole document.	1, 22.
X	WO 97/18343	1ST INSTANT. Figures 3 to 18. Pages 3, 10 to 16.	1, 22.
X	US 5876666	LIN et al. Figures 1 to 3. Column 7, line 34 to column 8, line 8. Column 9, line 22 to column 12, line 3.	1, 5, 15, 22.
X	US 5785934	JACOBS et al. Figures 1 to 3. Column 8, line 33 to column 9, line 7. Column 10, line 21 to column 13, line 11.	1, 5, 15, 22.
X	US 5674450	LIN et al. Figures 1 to 3. Column 7, line 31 to column 8, line 5. Column 9, line 19 to column 12, line 4.	1, 5, 15, 22.
X	US 4265747	COPA et al. Whole document.	1, 15, 17, 22, 23.

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.